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Unmasking the surgeons: the evidence base behind the use of facemasks in surgery

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Summary

The use of surgical facemasks is ubiquitous in surgical practice. Facemasks have long been thought to confer protection to the patient from wound infection and contamination from the operating surgeon and other members of the surgical staff. More recently, protection of the theatre staff from patient-derived blood/bodily fluid splashes has also been offered as a reason for their continued use. In light of current NHS budget constraints and cost-cutting strategies, we examined the evidence base behind the use of surgical facemasks.

Examination of the literature revealed much of the published work on the matter to be quite dated and often studies had poorly elucidated methodologies. As a result, we recommend caution in extrapolating their findings to contemporary surgical practice. However, overall there is a lack of substantial evidence to support claims that facemasks protect either patient or surgeon from infectious contamination. More rigorous contemporary research is needed to make a definitive comment on the effectiveness of surgical facemasks.

Keyword

Surgery

Picture a surgeon operating in a theatre, and chances are that you will imagine them wearing a surgical facemask. Masks are a quintessential part of the surgical attire that has become so deeply ingrained in the public perception of the profession. However, even today, it remains unclear as to whether they confer any tangible benefits to surgical outcomes. As 'efficiency' and 'cost-cutting' have increasingly become the *topics du jour* in the National Health Service, it seems reasonable to assess the efficacy, effectiveness and cost-to-benefit ratio for this particular component of the surgical uniform.

Methodology

We searched the PubMed journal database and Google Scholar with the search terms 'surgical facemask/mask', 'splash', 'contamination', 'infection' and 'outcomes' in order to identify salient publications. We also searched the guidance on surgical site infection from the National Institute for Health and Care Excellence. Furthermore, a manual search of reference lists from relevant papers was performed.

Contemporary attitudes to the surgical mask

A contemporary questionnaire-based study, which attempted to assess the attitudes of surgeons, revealed that 96% of responders wore facemasks.[1] About equal numbers did so with the primary aim of protecting the patients compared to protecting themselves. However, it was also found that 20% of responding surgeons wore the mask for the sole purpose of respecting tradition. Furthermore, 30% of responding surgeons felt that masks could make surgery more difficult by increasing breath condensation on spectacles, endoscopes and microscopes and thereby obscuring vision.

In May 2014, the first installation of the Glass Surgery project was broadcast to viewers around the world. This project, based at the Barts and the London School of Medicine and Dentistry, was the first of its kind to live-stream a surgical procedure, using new Google Glass technology, to any medical student or trainee with an internet connection. Mr Ahmed, the lead colorectal surgeon, elected not to wear a mask while performing the open right hemicolectomy and partial liver resection in question. In the immediate aftermath of the broadcast, Mr Ahmed came under scrutiny from various medical comment threads, blogs and chat rooms on the Internet questioning his decision to omit the facemask and whether this might have compromised patient safety.

Protection of the patient

The facemask has been used in surgical settings for over a hundred years;[2] first described in 1897, at its

inception, it consisted merely of a single layer of gauze to cover the mouth,[3] and its primary function was to protect the patient from contamination and surgical site infection. This practice was substantiated, at the time, by a recent discovery which demonstrated that bacteria could be disseminated from the nose and mouth during normal conversation as observed by bacterial colony growth on strategically placed agar plates in theatres. In the 1940s and 1950s, antibiotics and aseptic technique came to the forefront of infection control strategies within the surgical setting. Until recently, it has remained unclear as to whether bacterial colony growth on an agar plate was a direct correlate of surgical site infections and also whether the purpose of the surgical mask has been superseded by more modern strategies of infection control.

In order to advocate the validity of an intervention in medicine, it must satisfy three levels of evidence: efficacy, effectiveness and cost-effectiveness.[4] In the context of facemask, efficacy is whether masks prevent the propagation of droplets derived from the mouth and nose of the operating staff. Effectiveness is whether efficacy translates into a significant reduction in surgical site infection morbidity and mortality. And finally, cost-effectiveness determines whether the cost-to-benefit ratio of this effect would be desirable compared to an alternative course of action.

Intuition would suggest that facemasks offer a physical barrier preventing the emanation of droplets from the oral or nasal passages and therefore satisfy the efficacy requirement of the evidence ladder. However, there are a number of different hypotheses as to why this may not be the case. 'Venting' is a phenomenon whereby air leaks at the interface between mask and face which can act to disperse potential contaminants originating from the pharynx.[5] The accumulation of moisture, during prolonged usage, may exacerbate this problem by increasing resistance to air flow through the filter itself. Moisture accumulation is also thought to facilitate the movement of contaminants through the material of the mask itself by capillary action. These bacteria can subsequently be dislodged by movement. Friction at the face/mask interface has also been demonstrated to disperse skin scales which can further contribute towards wound contamination.[6]

In the modern era, there has also been a scarcity of experimental evidence to support the effectiveness of facemasks in the prevention of surgical site infections. The earliest retrospective studies[7] failed to demonstrate any statistically significant improvement in surgical site infection rates following the use of masks. Indeed, the latest National Institute for Health and Care Excellence guidelines on the matter do not require operating staff to wear a mask in theatre.[8] This decision was based primarily upon the findings of a Cochrane systematic review.[9] This review was guided by the findings of two particular randomised/quasi-randomised control trials.[10,11] The latest update of this review,[12] which was amended after the publication of current National Institute for Health and Care Excellence guidelines, included one further study.[13]

The Cochrane review[12] searched through six established databases (Appendix 1) looking for randomised control trials and quasi-randomised control trials investigating surgical outcomes comparing the use of disposable surgical masks with the use of no masks. The authors limited the scope of their analysis only to patients undergoing clean procedures (whereby the operating procedure does not enter a body cavity or viscus normally colonised by bacteria). The review chose not to investigate the role of mask in clean-contaminated, contaminated or dirty wounds as one would expect that masks would contribute less towards the prevention of surgical site infections under such circumstances. Primary outcomes of postoperative surgical wound infection and secondary outcomes of costs, length of hospital stay and mortality rates were ascertained.

Three studies were identified as fulfilling all the selection criteria of the review.[10,11,13] A total of 2106 participants were identified across the three studies (Table 1). All the studies reported on the primary outcome of postoperative surgical wound infection, none of the studies reported on any of the secondary outcomes. Furthermore, identified studies were assessed for risk of bias based on eight specific criteria (Table 2).

Statistical analysis of the extracted data revealed no statistically significant association between mask usage and the incidence of surgical site infection. The study concluded that 'it is unclear whether the wearing of surgical facemasks by members of the surgical team has any impact on surgical wound infection rates for patients undergoing clean surgery'. However, each of the studies included could be criticised for risk of bias (Table 2). Indeed, the Webster study, arguably the most rigorous of the three, only investigated the impact of mask on non-scrubbed members of the surgical team. There is uncertainty over whether the findings of some of these studies are applicable to contemporary surgical practice.

Based upon the findings of this review, National Institute for Health and Care Excellence guidelines state that there is 'limited evidence concerning the use of non-sterile theatre wear' such as surgical masks when trying to minimise the risk of surgical site infection, although there was an overall 'consensus that wearing non-sterile theatre wear is important in maintaining theatre discipline'. This latter

Table 1. Characteristics of included studies.[12]

Study	Methods	Participants	Outcomes	Notes
Chamberlain and Houang[10]	Quasi-randomised controlled trial	41 female patients undergoing gynaecology surgery. 24 clean and 17 non-clean. Of the clean surgeries: masked cohort $n = 14$, unmasked cohort $n = 10$	Wound infection defined as serious enough to warrant antibiotics in 2 cases and via high vaginal swab in third case. Follow-up until discharge only. No postoperative wound infections in the masked group and 3/10 (30%) in the non-masked group (no statistically significant difference: OR 0.07, 95% CI 0.00–1.63)	Study discontinued due to 3 surgical wound infections in unmasked group, although not proven as causal. Data extracted for clean surgery only. Unit of analysis error present.
Tunevall[11]	Quasi-randomised controlled trial	3088 patients undergoing general, vascular, breast, acute and elective surgery. 1429 clean and 1659 unclean. Of the clean surgeries: masked cohort $n = 706$, unmasked cohort $n = 723$	Wound infection defined as visible pus and/or cellulitis without pus requiring debridement, drainage and/or antibiotics. Duration of follow-up not stated but until after discharge from ward. 13/706 (1.8%) postoperative wound infections in the masked group and 10/723 (1.4%) in the non-masked group (no statistically significant difference: OR 1.34, 95% CI 0.58–3.07)	Data extracted from clean surgery only. Patients had 2 to 3 body washes preoperatively with 4% chlorhexidine prior to elective surgery. In most acute cases, at least one body wash was given. Unit of analysis error present.
Webster et al.[13]	Randomised controlled trial	811 patients undergoing gynaecological, obstetric, general (open), general (laparoscopic), urology and breast surgery. 660 clean and 151 non-clean. Of the clean surgeries: masked cohort $n = 313$, unmasked cohort $n = 340$	Wound infection defined by criterial used by National Nosocomial Infection Surveillance System of Australia. Clean surgery masked cohort, mean follow-up 33.4 days (SD 22.1). Clean surgery unmasked cohort, mean follow-up 33.4 days (SD 22.8). Infection rate 33/313 (10.5%) in the masked group and 31/340 (9.1%) in the non-masked group (no statistically significant difference: OR 1.17, 95% CI 0.70–1.97)	Scrubbed staff were not included in trial. Data extracted from clean surgery only. Missing data for 7 clean cases. Unit of analysis error present.

statement seems to be a rather vague and likely unfounded assertion which implies a correlation between dress code, staff discipline and thereby patient safety outcomes. This may reflect a reluctance among the medical profession to deviate from embedded tradition as reflected in Leyland and McCloy's questionnaire study.[1] Alternatively, it may reflect a prevailing intuition that surgical masks ought to protect against surgical site infections.

Table 2. Assessment for risk of bias in included studies.[12]

Study	1	2	3	4	5	6	7	8	9
Chamberlain and Houang[10]	?	?	?	L	L	L	?	H	?
Tunevall[11]	H	H	?	H	L	L	?	L	L
Webster et al.[13]	L	L	L	L	?	L	L	L	L

L: low risk; ?: uncertain risk; H: high risk.
Bias was assessed by the following aspects: (1) method of randomisation: how the randomisation schedule was generated, the method of randomisation, e.g. envelopes, computer etc., (2) allocation concealment, (3) blinding of patients (recipients), (4) blinding of outcome assessors to wearing of masks, (5) extent of loss to follow-up and use of intention-to-treat analysis, (6) source of funding, (7) selective reporting, (8) early stopping and (9) baseline comparability of treatment and control groups.

Unfortunately, publically available information regarding the financial costs of facemask usage on the National Health Service is lacking. However, as part of the Freedom of Information Publication Scheme, the data are available for the West Hertfordshire Hospitals NHS Trust which purchased 44,482 single-use facemasks in 2012.[14] During this year, the West Hertfordshire Hospitals NHS Trust performed a total of 63,250 operative procedures or interventions.[15] Extrapolation to the 10,594,814 total operative procedures and interventions carried out across NHS England during the same period[15] would equate to an annual procurement of almost 7.5 million single-use masks across hospitals in England. The NHS Atlas of Procurement lists the per unit expenditure of surgical facemasks to be between £0.34 to £1.22, depending on trust and supplier.[16] This suggests that annual NHS England expenditure on facemasks lies somewhere in the region of £2.5 to £9.1 million.

Hospital-acquired infections, of which surgical site infections are a subset, are a major problem for all health systems. Media coverage, in recent times, has heightened public awareness of their associated morbidity and mortality. Their socioeconomic impact is also substantial,[17] and it is estimated that iatrogenic infection increases the duration of average hospital stay by a factor of 2.5 while incurring almost three times the monetary cost of uninfected patients. Across the whole of the United Kingdom, it is estimated that annually hospital-acquired infections cost the National Health Service almost £1 billion in excess expenditure and a loss of 3.6 million bed days. Personal costs for the patients are also affected as their return to normal daily activity and employment are delayed.

Given the uncertainty in effectiveness of facemasks in preventing surgical site infection, it is impossible to perform a cost-to-benefit analysis on mask usage. It is clear, however, that the National Health Service expenditure on facemasks is a mere fraction of the costs incurred due to hospital-acquired infections.

Protection of the surgeon

An increasingly prevalent belief, in favour of mask usage, is the idea that they also confer some degree of protection to the operating staff from patient-derived infectious material.[18] Most obviously, they can act as a physical barrier against blood and bodily fluid splashes during surgery. One prospective study revealed that facemasks prevented blood/bodily fluid splashes that would have otherwise contaminated the surgeon's face in 24% of procedures.[19] The incidence of blood/bodily fluid splashes varies substantially between settings and between individuals. The risk is modified by the role of surgical staff (lead surgeons are at higher risk than first assistants, who in turn have a higher risk than scrub nurses), by surgical specialty as well as by surgical technique.[19,20] The frequency of blood/bodily fluid splashed has been reported to be as high as 62.5% in lead surgeons performing Caesarean section.[20]

Despite clear evidence that facemasks act to protect the theatre staff from macroscopic facial contamination, there are studies to suggest that they fail to protect surgeons from potentially hazardous submicrometre contaminants.[21] This corresponds roughly to the size range of infectious bacteria while viruses are even smaller. Therefore, the protection that masks confer in the form of macroscopic facial contamination may not necessarily extend towards any microscopic infectious agents present within that contamination.

Proponents of the surgical facemask may argue that even if they fail to completely negate the risks of infection they are likely to reduce exposure in a dose-dependent manner. While this field has not been extensively investigated, preliminary work suggests that facemasks fail to confer any degree of protection from infection due to streptococcal and staphylococcal bacterial species[22] or hepatitis B virus.[23] Furthermore, a facemask splash may promote a false sense of security, as surgeons may be less likely to report these as an

occupational exposure to bodily fluid compared to frank facial contamination.

Tying things together

In surgery, there are many aspects of current clinical practice that do not necessarily have an established evidence base. Indeed, it is permissible to bypass the evidence ladder when an intervention is so convincing that it is possible to discern its effect signal from noise by observation alone.[24] In such circumstances, interventions have a very clear mechanistic cause and effect relationship. Historically, it may have been thought that surgical masks fulfilled such criteria. This would explain why published literature examining surgical mask effectiveness has been lacking despite their ubiquitous nature within the surgical profession.

What literature that is available on the subject tends to be dated with poorly explained methodology. There is also uncertainty over whether the results of such studies can be extrapolated to current surgical practice given the advent of new antiseptic techniques since they were completed. The evidence base investigating the effects of facemask usage on patient-based outcomes is, in general, more extensive than that of surgeon-centred outcomes. Facemasks do have a clear role in maintaining the social cleanliness of surgical staff, but evidence is lacking to suggest that they confer protection from infection either to patients or to the surgeons that wear them.

Given that there is no evidence that they cause any harm either, proponents would rather err on the side of caution and encourage their continued use, stressing that there is no room for complacency when it comes to ensuring patient safety.[25] This opinion is similarly echoed by the National Institute for Health and Care Excellence guidelines which assert that mask usage contributes towards 'maintaining theatre discipline'.

Another unavoidable aspect of this debate is that of public perception. In the public psyche, facemasks have become so strongly associated with safe and proper surgical practice that their disposal could cause unnecessary patient distress. Indeed, the response on various medical forums following Mr Ahmed's decision not to wear a mask during his broadcasted surgeries would reflect the prevalence of such a belief among the public.

It is clear that more studies are required before any absolute conclusions can be drawn regarding the effectiveness or, indeed, ineffectiveness of surgical masks. The published literature does suggest that it may be reasonable to further examine the need for masks in contemporary surgical practice given the interests of comfort, budget constraints and potential ease of communication, although any such study would undoubtedly have to be large and well controlled to prove causality given the low event frequency of surgical site infections. It is possible, if not probable, that if surgical facemasks were to be introduced today, without the historical impetus currently associated with their use, the experimental evidence would not be sufficiently compelling to incorporate facemasks into surgical practice.

However, when current surgical practice is the culmination of layer upon layer of precautions in the hope of preventing surgical site infection, do we dare to experiment with their omission to see if they have any tangible consequence on morbidity and mortality? A randomised control trial investigating the uncertainty surrounding prophylactic antibiotic use in clean coronary artery surgery turned out to be catastrophic – the study had to be terminated early for ethical reasons due to an unacceptable increase in postoperative infection in the placebo cohort.[26] Perhaps an annual expenditure of a few million pounds in a healthcare budget of almost £100 billion is a small price to pay for an intervention of unknown but potentially dramatic effectiveness.

It is important not to construe an absence of evidence for effectiveness with evidence for the absence of effectiveness. While there is a lack of evidence supporting the effectiveness of facemasks, there is similarly a lack of evidence supporting their ineffectiveness. With the information currently available, it would be imprudent to recommend the removal of facemasks from surgery. Instead, in the medical field where common practice can so easily become dogma, it is necessary to recognise the constant need to maintain a healthy scepticism towards established beliefs and to periodically re-evaluate and critically assess their scientific merit.

Declarations

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Appendix 1. Databases included in the search strategy[12]

The Cochrane Wounds Group Register (searched 23 October 2013)
The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library 2013*, Issue 9)
Ovid MEDLINE (1946 to October Week 3 2013)
Ovid MEDLINE (In-process and other non-indexed citations, October 23, 2013)
Ovid EMBASE (1974 to 23 October 2013)
EBSCO CINAHL (1982 to 18 October 2013)